

United States District Court  
Eastern District of New York

1:18-cv-06650-CBA-SJB

Jose Melendez, Jane Doe, individually and  
on behalf of all others similarly situated

Plaintiffs

- against -

One Brands, LLC

Defendants

Plaintiffs' Memorandum of Law in Opposition  
to Defendant's Motion to Dismiss

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## INTRODUCTION

Plaintiffs submits this memorandum of law in opposition to defendant's Motion to Dismiss the First Amended Complaint ("FAC" or ECF No. 16), and Memorandum of Law in Support ("Def. MOL"). For the reasons below, the motion should be denied in its entirety.

### I. FACTUAL BACKGROUND

This case arises out of Defendant's violations of New York State General Business Law ("GBL"), GBL §§ 349-350. Plaintiff alleges that Defendant deceptively marketed its One Bar protein bars by making material misrepresentations and omissions on One Brands' website and on the front of each One Bar label. FAC ¶ 23.

The representations violate New York General Business Law ("GBL") §§ 349 and 350, prohibiting "[d]eceptive acts or practices" and "[f]alse advertising" because they contain unauthorized implied nutrient content claims ("low sugar") under the guise of "factual statements" and a brand name. FAC, ¶¶ 51-69.

The purpose of these laws is "to secure an 'honest market place' where 'trust,' and not deception, prevails." *Goshen v. Mutual Life Ins. Co. of N.Y.*, 774 N.E.2d 1190, 1195, 98 N.Y.2d 314, 324 (2002) (citation omitted).

To state a claim pursuant to GBL §§ 349 and 350, a plaintiff must allege that: (1) the defendant's deceptive acts were directed at consumers, (2) the acts are misleading in a material way, and (3) the plaintiff was injured as a result. *See, e.g., Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 25 (1995). Whether a particular act or practice is deceptive is intensely-factual, and, therefore, motions to dismiss are disfavored. *See, e.g., Sims v. First Consumers Nat. Bank*, 303 A.D. 2d 288, 289, 758 N.Y.S. 2d 284, 285-286 (1st Dept. 2003).

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), quoting *Bell Atl. Co. v. Twombly*, 550 U.S. 544, 570 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*, citing *Twombly*, 550 U.S. at 556.

“The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Id.*, quoting *Twombly*, 550 U.S. at 556-57; *Williams v. Calderoni*, 2012 U.S. Dist. LEXIS 28723, at \*20 (S.D.N.Y. Mar. 1, 2012) (in evaluating a complaint under a Rule 12(b)(6) standard, the Court need not accept “implausible allegations or legal conclusions expressed as facts”), *aff’d*, *Williams v. Schwartz*, 529 F. App’x 89 (2d Cir. 2013).

Marketed to consumers seeking low-sugar protein bars, each One Bar’s label prominently states that the bar within contains only one gram of sugar. FAC at ¶¶ 5-9. Low-sugar content is also the central marketing focus of the One Bar websites. *Id.* ¶ 8.

Defendant does not argue that if what Plaintiff alleges is true, then Plaintiff has failed to state a claim. Rather, Defendant argues that (1) there are no restrictions about what claims can be made about sugar content, (2) if there are any limitations on sugar claims, defendant complied with them and (3) plaintiff cannot allege the Products have *more* sugar than represented because Plaintiff failed to test a 12-bar sample in conformance with FDA labeling requirements.

## **II. “ONE GRAM OF SUGAR” AND “ONE BAR” ARE NOT PREEMPTED CLAIMS**

Defendant advances the standard shotgun preemption arguments (“all claims are

preempted by federal law”), express preemption (“Because the claim [statements about sugar] is expressly authorized under federal law, Plaintiff’s challenge to it is preempted”) and implied preemption MOL at 14 (“Federal law sets the parameters of any sugar-content claim that Plaintiff can assert here.”); *In re PepsiCo, Inc. Bottled Water Mktg. & Sales Practices Litig.*, 588 F.Supp.2d 527, 530 (S.D.N.Y. 2008) (describing differences between express and implied preemption).

Federal law explicitly bars state and local governments from adopting food labeling requirements that are “not identical to” the federal requirements established by the Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (“NLEA”); 21 U.S.C. § 343-1(a)(1)-(5) (“no state or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce” where federal standards are established).

In the context of the FDCA, “express preemption and implied pre-emption create a ‘narrow gap’ through which a plaintiff’s state-law claim must fit if it is to escape express or implied pre-emption.” *Elkind v. Revlon Consumer Prods. Corp.*, 14-cv-2484, 2015 WL 2344134, at \*3 (E.D.N.Y. May 14, 2015).

### **III. NO REGULATIONS AUTHORIZE OR PERMIT AN IMPLIED “LOW SUGAR” CLAIM**

Defendant attempts to escape liability by pointing to 21 C.F.R. § 101.13. Def. MOL at 2 (“Plaintiff is looking to the wrong regulation [21 C.F.R. § 101.60]. 21 C.F.R. § 101.13 specifically authorizes ONE Brands to state the amount of nutrients, like sugar, on its labeling. Because the claim is expressly authorized under federal law, Plaintiff’s challenge to it is preempted.”).

In pointing to the calorie-related claims provided as an example in § 101.13(i), defendant acknowledges but misstates the relationship with Section 101.60. Def. MOL at 19, fn7 (“Section 101.60 does not override this provision [101.13]”).



21 C.F.R. § 101.13 (“general principles”) provides a framework for types of nutrient content claims that are further fleshed out in separate regulations. 21 C.F.R. §§ 101.54-101.69 (“Subpart D—Specific Requirements for Nutrient Content Claims”).

These regulations set the boundaries of when “[A] claim about the calorie or sugar content of a food may [only] be made on the label. 21 C.F.R. § 101.60(a). Specifically, claims for the absence of (“no...”), and relative (“fewer calories,” “less sugar”) amounts, of calories and sugar, are authorized, but a straight “low sugar” claim is specifically absent.

	<u>Calorie Claims<sup>1</sup></u>	<u>Sugar Claims<sup>2</sup></u>
Absence	No Calories	No Sugar
Relative	Fewer Calories	Less Sugar
Low	Low Calories	X

According to defendant, its statements about sugar are no different than the statements “‘100 calories” or ‘5 grams of fat”’ on the principal display panel...a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient.” Def MOL at 19, 58 Fed. Reg. 3, 2302 at 2310 (Jan. 6, 1993).

However, defendant does not present “one gram of sugar” as a “simple statement of amount.” 58 Fed. Reg. 3, 2302, 2310 (Jan. 6, 1993) (“FDA finds that there are some circumstances in which an amount claim cannot be considered to characterize in any way the level of a nutrient in a food. For example, the statement “100 calories” or “5 grams of fat” on the principal display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient. As long as such a statement is not false or misleading, it can appropriately be included in food labeling.”).

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<sup>1</sup> 21 C.F.R. § 101.60(b)

<sup>2</sup> 21 C.F.R. § 101.60(c)

Rather, defendant's "1g of sugar" is touted in comparison to its 20g of protein, and its website describes this protein to sugar combination as "20 grams of protein and *only* 1 gram of sugar," and that "just 1 gram of sugar, you can celebrate." FAC at 7, 9.

The calorie-related claim ("100 calories") in 21 C.F.R. § 101.13(i)(3) is permitted because such a calorie amount has no special significance to consumers such that its use could be misleading in the same way that a claim understood as "low sugar" could be, and is.

Because "low sugar" claims have never been authorized, they are prohibited. 58 Fed. Reg. 2302, 2368 ("The agency stated that under the provisions of the statute, such implied claims are prohibited until they are defined by FDA by regulation."); *see also* FDA Warning Letter to CK Management, Inc., May 19, 2015 ("The labeling for your "Fruit of the Spirit" product, located on the website [url omitted] contains the nutrient content claim "Low sugar." While FDA has defined some nutrient content claims for sugar in 21 CFR 101.60(c), FDA has not defined "Low sugar"; therefore, the use of this claim misbrands your product under section 403(r)(1)(A) of the Act. The claim "lower sugar" may be used...") *but see Colella v. Atkins Nutritionals, Inc.*, 348 F.Supp.3d 120, 135-36 (E.D.N.Y. 2018) (a claim alleging that a "net carbs" statement was misleading was preempted since FDA never prohibited that statement).

#### **IV. "ONE BAR" AND "ONE GRAM OF SUGAR" ARE IMPLIED NUTRIENT CONTENT CLAIMS**

The brand name, "One Bar" and the front label claim, "One Gram of Sugar," are implied nutrient content claims. Defendant is correct that "ONE Brands makes no explicit "low sugar" claim, which is why the FAC characterized "One Gram of Sugar" as an implied nutrient content claim. Def. MOL at 19 ("'[L]ow sugar' appears nowhere on the ONE Bar" and "is entirely Plaintiff's creation.") compare with FAC ¶ 16 ("The representations as to the one gram of sugar are *understood by consumers* to indicate the Products are "low sugar.") (emphasis added).

With respect to the implied nutrient content claim in the product name, the FAC mistakenly cited the section of the U.S. Code as opposed to the identical section in the C.F.R. FAC 17, (“The Products’ brand name, “ONE,” is an unauthorized implied nutrient content claim, as the “ONE” refers to the “low sugar” content of the Products. 21 U.S.C. § 101.69(b)(3).”).

21 C.F.R. § 101.69(b)(3) is relevant because it applies to the approval process for the use of a “new (heretofore unauthorized)” implied nutrient content claim (“low sugar”) in a brand name (“One Bar”).

“One Bar” appears as a reincarnation of “Carbolite,” a brand which sought approval for its “low carbohydrate” claim in its name over 15 years ago. 67 Fed. Reg. 236, 72963, Food Labeling: Nutrient Content Claims; Implied Nutrient Content Claim in the Brand Name CARBOLITE; Availability of Petition (Dec. 9, 2002); Docket No. 02P-0462.

In denying the Carbolite petition, the FDA concluded that that none of its proffered phrases – “low in sugar,” “low sugars,” “low in carbohydrates” or “low carbohydrates” – were “an approved nutrient content claim, and should not be interpreted or implied as such from this letter. FDA/CFSAN Response to Carbolite Foods, Inc. - Petition Denial, Jan. 15, 2003 at p. 3, fn 3.

The FDA determined that “[T]he term “carbo” in “Carbolite” suggests that the nutrient that the implied claim refers to is ‘carbohydrates,’” in the same manner as the “one” in “One Bar” refers to sugar. *Id.* at p.4. And Carbolite’s “sugars have been replaced with sugar alcohols” in the same way the One Bar has done, save for the “one gram” of real sugar.

## **V. CONNECTION OF SUGAR TO CALORIES AND CARBOHYDRATES IS LONG-ESTABLISHED**

While there are several differences between the claims of Carbolite and One Bar, the common theme is that both are aimed at consumers seeking products that are useful in “weight

control,” through consumption of fewer calories.

Defendant finds it implausible that “consumers would be led to believe that a product with only one gram of sugar is also low in carbohydrates.” Def. MOL at 20 citing FAC ¶ 21. In fact, Section 105.66 originally included “terms such as low calorie, ‘reduced calorie,’ and ‘sugar free,’ which were thought to be useful attributes of a food in the maintenance or reduction of body weight.” 56 Fed. Reg. 229, 60421 at 60457, Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms (Nov. 7, 1991) (21 CFR Parts 5, 101, and 105); FDA, Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Sugar Free Claims, Sept. 2007 (“FDA has historically taken the position that consumers may associate claims regarding the absence of sugar with weight control and with foods that are low calorie or that have been altered to reduce calories significantly.”); see FAC ¶ 19 (“Reasonable consumers “clearly link sugar to calories and therefore expect a reduction in sugar content to deliver a reduction in calorie content.” N. J. Patterson et al., *“Consumer understanding of sugars claims on food and drink products.”* Nutrition bulletin 37.2 (2012): 121-130 (“In focus groups, participants felt deceived if sugar reduction claims were being made without a significant reduction in calories.”)).

As the qualities of maintaining a healthy body weight became more scientifically supported and accepted as public health and individual goals, it was no longer accurate that they be described in connection with “special dietary uses.” 56 Fed. Reg. 229, 60421 at 60457 (“Consequently, the agency is proposing to place requirements for terms such as “low” and “reduced calorie,” comparative claims, and sugar claims, originally provided for in § 105.66, in § 101.60”).

## **VI. DEFENDANT MISINTERPRETS PLAINTIFF’S USE OF SUGAR TESTING**

Defendant miscasts the argument of the FAC. Compare Def. MOL at 1, “Plaintiff’s

primary theory is that ONE Brands' one gram of sugar statement is false based on "independent testing" with FAC, 23, "The Products' representations are misleading due to promoting the low sugar ("one gram") content, which is false (laboratory testing) and misleading (no authorized nutrient content claim for "one gram" of sugar, or low sugar."

The FAC is clear that even if the sugar content is accurate, the Products still contain the misleading and unauthorized implied nutrient content claim ("low sugar").

A. The FDA Prescribed Methodology is Inapplicable

Defendant misleadingly claims that Plaintiff must follow the FDA testing methodology in to show the representations as to sugar content are false and misleading under New York consumer protection laws. Def. MOL at 3 citing 21 C.F.R. § 101.9(g) (a "sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot" in accordance with "appropriate methods as given in the "Official Methods of Analysis of the AOAC International").

Plaintiff did not, however, have access to 12 different randomly chosen shipping cases. Manufacturers, not consumers have access to shipping cases. To hold that a consumer is required to follow the testing described in Section 101.9(g) to state a plausible claim for relief under New York's consumer protection laws would allow manufacturers to include deceptive labeling claims with impunity.

In fact, not even defendant is required to use the testing methodology set forth in Section 101.9(g) to ensure compliance with FDA food labeling requirements. In "Guidance for Industry: A Food Labeling Guide," the FDA provides answers to food labeling questions including the following:

**N32. How many samples of each product should we analyze for nutrition labeling?**

**Answer:** FDA has not defined the number of samples that must be analyzed. It is the responsibility of the manufacturer/packer/distributor to determine the variability of their product(s) and the number of samples needed to provide accurate nutrient data .... FDA, may be of assistance in this area. FDA will use a composite of 12 units when performing enforcement analyses.

Guidance for Industry: A Food Labeling Guide, p. 39, Apr. 2008

Defendant resorts to a futile attempt at semantics, noting that the FAC's admitted testing was only " 'based upon' AOAC-approved methodologies" rather than complying with those methodologies. Def. MOL at 17.

B. Defendant's Authorities in Support of FDA Testing Protocols Distinguished

Defendant's claim that "every district court considering this issue..." required a plaintiff to use samples from 12 shipping cases to avoid preemption is inaccurate. The common thread between defendant's testing cases is that the claims were directed squarely at mandatory, nutritional disclosures. Def. MOL at 17 citing *In re: Whole Foods Market, Inc., Greek Yogurt Marketing and Sales Practices Litigation*, 163 F.Supp.3d 385 (W.D. Tex. Feb. 12, 2016) (where none of the 11 plaintiffs performed any testing and challenged the sugar content on the Nutrition Facts based on magazine article, dismissal was warranted); *Mee v. I A Nutrition, Inc.*, No. C-14-5006 MMC, 2015 WL 2251303, at \*3 (N.D. Cal. May 13, 2015) (plaintiff's challenge to protein content dismissed where testing directed to "Supplemental Facts" preempted and lab reports attached put the testing issue front and center); *Burke v. Weight Watchers Int'l, Inc.*, 983 F.Supp.2d 478 (D.N.J. 2013) (product testing showed calorie count discrepancy from Nutrition Facts, but *within* the 20% "safe harbor" established by 21 C.F.R. § 101.9(g)(5)); *Baker v. NNW, LLC*, 4:15-cv-00222, 2015 WL 12843827, at \*4 (W.D. Mo. July 8, 2015) (dismissing claims "premised on the argument that the nutritional labels on the packages of Healthy 100% Whey were deceptive").

C. Lab Testing Not Intended as Dispositive, But as a “Nudge”

The FAC does not invoke the results of its independent, AOAC testing, to show that the amount of sugars “is greater than 20 percent in excess of the value for that nutrient.” Def. MOL at 4.

A private party’s failure to comply with guidelines intended for manufacturers would be relevant if it was a “close call” and the Products were alleged to have 1.5 or 2 grams of sugar as opposed to one. But plaintiff’s analysis revealed *five* grams, a 500% deviation from the front label claim. FAC.

Moreover, the testing is intended to allow the Court to “infer that tests conducted in compliance with the 12-sample methodology would support Plaintiff’s allegations that the Product is mislabeled.” *Smith v. Allmax Nutrition, Inc.*, 2015 U.S. Dist. LEXIS 1717897 at \*22 (E.D. Cal. Dec. 24, 2015).

By alleging that his own independent results demonstrate higher sugar content levels than marketed by Defendant, Plaintiff has pled “factual allegations enough to raise a right to relief above the speculative level” and give defendant “fair notice” of the claim and “the grounds upon which it rests.” *LeChase Constr. Servs., LLC v. Escobar Construction, Inc.*, 3:18-cv-01021 (N.D.N.Y. July 1, 2019); *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (citing *Twombly*). Whether more detailed testing through discovery reveals the Products’ front label claims of sugar content are consistent with plaintiff’s laboratory results is more appropriately “an issue of proof, and Plaintiff does not need to prove his case at the pleading stage of the case.” *Gubala v. CVS Pharmacy, Inc.*, 14-cv-9039, 2016 U.S. Dist. LEXIS 32759, at \*28 (N.D. Ill. Mar. 15, 2016)

; see also *In re Herbal Supplements Mktg. & Sales Practices Litig.*, 2017 U.S. Dist. LEXIS 76207 at \*47 (N.D. Ill. May 19, 2017) (accepting plaintiff’s testing results and recognizing the defendants are “free to challenge the efficacy of [the] testing later in the litigation”)

## **VII. NATIONWIDE CLASS ALLEGATIONS ARE SUFFICIENT AT THE PLEADING STAGE**

Defendant's argument with respect to deferring decision on whether plaintiff is adequate as a representative of a nationwide class are correct. Def. MOL at 11 ("At this stage, there is no need to address Plaintiff's allegation that he is a representative plaintiff for a nationwide class of ONE Bar consumers."); *In re Frito-Lay N. Am., Inc. All Nat. Litig.*, 2013 WL 4647512, at \*57 ("courts have recognized that this question is usually addressed on a class certification motion") (emphasis added).

The question will not be whether the named plaintiffs actually satisfy predominance, but whether Defendant has demonstrated that it will be impossible—after full discovery—for Plaintiffs to satisfy Rule 23. *Motta v. Glob. Contract Servs. Inc.*, 15-cv-8555, 2016 WL 2642229, at \*5 (S.D.N.Y. May 4, 2016).

## **VIII. PLAINTIFF HAS STANDING TO SEEK INJUNCTIVE RELIEF**

Plaintiffs and reasonable consumers seek to be relieved from Defendant's continuing misleading and deceptive practices in the future, which is no more truthful today than when plaintiff first discovered the alleged deception. *Ackerman v. Coca-Cola Co.*, 09-cv-395, 2013 WL 7044866, at \*15 n. 23 (E.D.N.Y. July 18, 2013); *see also, e.g., Koehler v. Litehouse, Inc.*, No. 12-cv-04055, 2012 WL 6217635, at \*6–7 (N.D. Cal. Dec. 13, 2012) (plaintiff had standing for injunctive relief claim even though he did not intend to purchase the product as advertised).

## **CONCLUSION**

Though "a party may amend its pleading only with the opposing party's written consent or the court's leave" after the expiration of time for amendment as a matter of course, the Court "should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2); *Foman v. Davis*, 371 U.S. 178, 182 (1962). "[T]he 'permissive standard' of Rule 15 'is consistent with [the Second



Circuit's] strong preference for resolving disputes on the merits.'" *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 171 (2d Cir. 2015). Plaintiffs have not had an opportunity to amend their pleading in response to a Court order evaluating the sufficiency of his allegations. As the Second Circuit observed, "[w]ithout the benefit of a ruling, many a plaintiff will not see the necessity of amendment or be in a position to weigh the practicality and possible means of curing specific deficiencies." *Loreley*, 797 F.3d at 190.

For the foregoing reasons, the Court should deny Defendant's Motion in its entirety or in the alternative, grant leave to amend or dismiss without prejudice.

Dated: July 12, 2019

Respectfully submitted,

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Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information, and belief, formed after an inquiry reasonable under the circumstances, the contentions contained in the annexed documents are not frivolous.

Dated: July 12, 2019

/s/ Spencer Sheehan  
Spencer Sheehan